

treatment with Peg/RBV compared with no treatment in PNALT/CHC. **METHODS:** Sustained viral response (SVR) was 40% for 48-week treatment in genotype 1 and 72% for 24-week treatment in genotype 2/3. Disease progression was modeled based on METAVIR scores F0 to F4, followed by cirrhosis complications and death. Mean fibrosis progression rates were derived from literature reports of biopsy series in patients with PNALT. The reference is a cohort of patients with mean age 45 years with PNALT and CHC, with distribution of fibrosis at baseline equal to that found in the trial. Quality of life and costs for each health state were based on literature estimates and on European treatment patterns. Costs in 2003 Euros and benefits were discounted at 3%. Sensitivity analyses on key clinical and economic parameters were performed. The analysis was reported from the perspective of a European National Health Service (Italian setting). **RESULTS:** In genotype 1, Peg/RBV compared with no treatment prolonged the time to cirrhosis by 4.8 years, increased life years (LY) by 1.4 and quality-adjusted life years (QALY) by 1 year. The incremental cost per QALY was 12,102€. In genotypes 2/3, Peg/RBV prolonged the time to cirrhosis by 8.6 years, increased LY by 2.5 and QALY by 1.8 years. The incremental cost per QALY was 1084€. Based on the distribution in the trial of 71% genotype 1, and 28% genotype 2/3, the overall CE ratio per QALY was 7419€. **CONCLUSIONS:** Treatment of adults with PNALT/CHC using Peg/RBV is projected to delay time until cirrhosis, increase life expectancy, and is cost-effective.

PGI6**ECONOMIC BURDEN OF GERD AND PUD IN AN EMPLOYED POPULATION**

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OBJECTIVES: The objective of this study was to evaluate the differences in reported levels of absenteeism and direct medical costs between employees diagnosed with gastroesophageal reflux disease (GERD) and/or peptic ulcer disease (PUD) and a matched-cohort with neither disease. **METHODS:** Data were extracted from the MarketScan Research Database, a Health Insurance Portability and Accountability Act compliant database consisting of medical and prescription claims of employees linked to the absenteeism files of their employers. Employees with an ICD-9 code for GERD/PUD, and a matched cohort with neither disease, were identified from January 1, 1997 to December 31, 2000. Demographic, absenteeism, and resource-utilization variables were collected for all eligible subjects. Analysis of variance was used to test the null hypothesis that the four populations have equal means of absenteeism rates. **RESULTS:** In all, 6205 employees with GERD, 2702 with PUD, 3297 with both GERD and PUD, and 42,902 matched control subjects were identified. There was no significant difference between the GERD and PUD groups in health care costs, except total prescription costs that were higher in the GERD group ($p < 0.001$). Work-absenteeism rates appeared to increase in the expected fashion, with lowest rates in the control group and highest rates in the combined group. The magnitude of this difference was 0.3 sickness-related absence days per individual per year between the groups with and without gastrointestinal disease. For all-cause absences, the difference was higher with 1.5 absence days per year. Projections of this data to an average sized Fortune 500 company of 250,000 employees would translate to total direct costs of \$312 million and indirect costs of

\$4.75 million per year. **CONCLUSIONS:** Direct medical cost and worker absenteeism, in GERD and PUD employees creates a significant burden on the employee community.

PGI7**FECAL LACTOFERRIN ASSAY FOR THE INITIAL DIAGNOSTIC APPROACH TO SYMPTOMATIC PATIENTS WITH ILEAL POUCH-ANAL ANASTOMOSIS: A COST-EFFECTIVENESS ANALYSIS**

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OBJECTIVES: Fecal lactoferrin (FL) is a non-invasive marker, able to distinguish between inflammatory and non-inflammatory causes of symptoms in patients with ileal pouch-anal anastomosis (IPAA). We assessed the cost-effectiveness (CE) of the FL assay as the initial screening test for the evaluation of symptomatic patients with IPAA. **METHODS:** The frequencies of pouchitis, irritable pouch syndrome, cuffitis, and Crohn's in symptomatic patients were estimated to be 50%, 36%, 7%, and 7% respectively. The FL assay has a sensitivity of 100% and a specificity of 85% (7 mg/ml threshold) to distinguish between inflammatory and non-inflammatory causes of symptoms. Four competing diagnostic strategies [empiric metronidazole therapy (txMTZ), initial pouch endoscopy/biopsy (testBiop), initial FL assay then MTZ when warranted (testFL + MTZ), and FL assay then pouch endoscopy/biopsy when warranted (testFL + Biop)] were modeled in a decision tree. Response rates to all therapies were based on current literature and expert opinion. Effectiveness equaled the number of days out of 30 that a patient received responsive therapy. Procedural and drug costs were estimated from the 2003 Medicare fee schedule and current average wholesale price, respectively. **RESULTS:** In the base case, the average cost per patient was \$244 for testFL + MTZ, \$251 for txMTZ, \$408 for testFL + Biop, and \$431 for testBiop. All competing strategies were more effective than test FL + MTZ, with incremental effectiveness ranging from 2.0 to 0.1 days at an incremental cost ranging from \$8 to \$1263. The incremental CE ratio for txMTZ and testFL + MTZ of only \$8 does not reflect unnecessary antibiotic exposure resulting in delayed diagnosis, adverse effects, antimicrobial resistance, or patient preference for the 50% relative decrease in invasive endoscopic procedures. Results were robust in multivariate sensitivity analyses. **CONCLUSIONS:** FL measurement prior to treatment with MTZ is a less costly strategy with only a marginal decrease in effectiveness when compared to empiric antibiotic therapy and other diagnostic strategies.

PGI8**A PHARMACOECONOMIC ASSESSMENT OF THE BENEFITS AND COSTS OF MANAGING IMMUNOSUPPRESSION IN POST-LIVER TRANSPLANT PATIENTS: A UNIVERSITY HOSPITAL PERSPECTIVE**

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OBJECTIVES: The overall aim of this investigation was to determine the best use of post-transplant immunosuppression therapies, in terms of clinical and economic outcomes, for the liver transplant population at the University of Colorado Hospital (UCH), regardless of expected reimbursement. **METHODS:** Patients were sequentially assigned to either tacrolimus (FK) or emulsified cyclosporine (CYA) with or without mycophenolate

mofetil (MMF) yielding four treatment arms: MMF + CYA (60), MMF + FK (51), CSA (39), and FK (41). All patients were followed for one year post-transplant. Using intent to treat or crossover analysis outcomes were similar between FK- and CYA-treated groups, allowing comparison of MMF patients (111) to no-MMF patients (80). Costs (included: hospital, clinic, emergency department, outpatient immunosuppression; excluded: physician fees) were obtained using relative value units (RVUs, microcosting), and wholesale acquisition prices. Ratios of cost-to-charges (RCCs) for cost-estimate method comparisons were obtained from a Medicare cost report. **RESULTS:** All treatment arms had similar severity and chronology of rejection episodes. In addition, there were no significant differences between treatment arms when actual costs (RVUs), or other cost-estimation methods were used. Cost-center specific ratio of costs to charges (RCCs) performed better than global hospital RCCs, but both were significantly different from, and underestimated, RVU costs. Pharmacy appeared to be the reason why cost-center specific RCCs did not perform well. There were no significant differences between cost-center specific RCCs and RVU costs when pharmacy RCCs were adjusted. **CONCLUSIONS:** There is not a preferred immunosuppressive treatment substitute (MMF + FK, MMF + CYA, FK, CYA) for the post-liver transplant population at UCH. Traditional cost-estimate methods do not accurately approximate costs. A pharmacy RCC adjustment may be required for disease states that use significant inpatient pharmacy resources. Cost-center specific RCC method cost-estimates may be improved with this methodology.

GI DISEASES/DISORDERS

GI DISEASES/DISORDERS—Quality of Life

PGI9

RESPONSIVENESS TO CHANGE AND ENGLISH LANGUAGE VALIDATION OF THE WPAI-GERD QUESTIONNAIRE-RESULTS FROM A CANADIAN STUDY

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OBJECTIVES: To assess responsiveness to change and construct validity of the English Work Productivity and Activity Impairment questionnaire for Gastro-Esophageal Reflux Disease (WPAI-GERD). **METHODS:** The WPAI-GERD was used in a clinical study in Canadian GERD patients with moderate or severe symptoms treated with esomeprazole 40 mg once daily for 4 weeks. Productivity variables obtained included GERD-specific absence from work, reduced productivity while at work, and reduced productivity while carrying out regular daily activities other than work during the preceding week. **RESULTS:** The analysis included 217 patients, of whom 71% (n = 153) were employed. Before start of treatment, employed patients reported an average of 0.9 hours absence from work and 14.0% reduced work productivity (= 5.8 hours equivalent; % reduced productivity x hours actually worked), as well as 21.0% reduced productivity in daily activities (all patients). After treatment, the corresponding figures decreased to 0.3 hours, 3.0% (= 1.1 hours equivalent) and 4.9%, respectively. Thus, the improvement (difference from start of treatment) in productivity was 0.6 hours (p

= 0.01) for absence from work, 11.0% units (p < 0.001) for reduced work productivity (= 4.7 hours equivalent, p < 0.001) and 16.1% units (p < 0.001) for reduced productivity in activities. This improvement translates into an avoided loss of work productivity of 5.3 hours in total on a weekly basis per patient employed. Cross-sectional correlation coefficients between WPAI variables and symptoms (range: 0.04–0.63), as well as health-related quality of life (range: 0.02–0.65) supported cross-sectional construct validity of the English WPAI-GERD. Corresponding change score correlations between WPAI variables and relevant symptoms were low (range: 0.10–0.23), which would indicate poor longitudinal construct validity. **CONCLUSIONS:** Cross-sectional construct validity of the English WPAI-GERD version was confirmed and results indicated that the WPAI-GERD is responsive to change. Although these results also indicated poor longitudinal construct validity, the overall findings suggest that further study of the instrument remains warranted.

PGI10

WORK LOSS AND ACTIVITY IMPAIRMENT DUE TO INFLAMMATORY BOWEL DISEASE

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OBJECTIVES: To evaluate lost productivity in Inflammatory Bowel Disease (IBD) patients from a large gastroenterology outpatient practice in an urban university hospital system. **METHODS:** A self-administered survey was mailed to 614 IBD patients. The survey included the WAI questionnaire (Work and Activity Impairment from IBD), a modified version of the WPAI (Work Productivity and Activity Impairment Questionnaire), which measures lost productivity in the form of missed work (absenteeism), impairment during work (presenteeism), and daily activity impairment during the past year. Additional questions pertaining to IBD disease severity, demographics, medical treatment, and comorbid conditions were included. Multiple regression models were used to assess the impact of IBD severity, age, gender, comorbidities, and disease type (Crohn's Disease or Ulcerative Colitis) on absenteeism, presenteeism, and activity impairment. **RESULTS:** Of the 314 respondents (51.1% response rate), 46.8% were female and 53.2% male (mean age 46.1 years). Respondents reported an average of 14.1% of scheduled work hours were lost due to absenteeism or disability. Among respondents who missed at least some work in the past year (n = 98; 31.2%), the mean number of hours missed was 56.4. On average respondents reported a 25.4% decrease in workplace productivity (presenteeism), and reported a 30.4% reduction in daily activity level due to IBD. Multiple regression analysis revealed that IBD severity, age and anemia were the most significant predictors of absenteeism (p < 0.05). For presenteeism, IBD severity, anemia and hypercholesterolemia were significant predictors (p < 0.05). Lastly, for daily activity impairment, IBD severity, female gender, and the comorbidities of anemia, arthritis, hypercholesterolemia, depression and anxiety were significant predictors (p < 0.05). In all three models, severity of IBD symptoms was the most important predictor of lost productivity. **CONCLUSIONS:** The severity of IBD is a significant determinant of productivity loss in the form of absenteeism from work, presenteeism at work, and daily activity impairment.